510(k) Summary of Safety and Effectiveness

Submitted by:	United Orthopedic Corporation
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Date of Summary:	July 15, 2013
Contact Person	Fang-Yuan Ho Regulation and Document Management
Proprietary Name:	UTF Stem-reduced, Additional Sizes
Common Name:	Hip stem
Device Classification Name and Reference:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis under 21CFR 888.3358 This falls under the Orthopedics panel.
Device Class	Class II
Panel Code	Orthopaedics Device
Device Product Code:	LPH, KWY, LZO
Predicate Device:	"UNITED" UTF Stem, Reduced (K123550)

AUG 3 0 2013

Device Description:

This subject device is a size extension to the cleared "UNITED" UTF Stem-Reduced (K123550). The indications, materials, design of this subject device are identical to the cleared "UNITED" UTF Stem-Reduced except for its large size. As the same as the cleared UTF Stem–reduced (K123550), the subjected device forged from Ti-6Al-4V alloy (ASTM F136), is a modular, wedge-shaped stem with 12/14 neck taper. The proximal part of each femoral stem is plasma coated with CP Ti powder (ASTM F1580).

Indications:

This device is indicated for use in total hip replacement or bipolar hip replacement undergoing primary and revision surgery for the following conditions: non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusion acetabuli, and painful hip dysplasia; inflammatory degenerative joint disease such as rheumatoid arthritis; correction of functional deformity; treatment of non-union, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques; revision procedures where other treatments or devices have failed.

This device is designed for cementless use.

Basis for Substantial Equivalence:

The subject device is a size extension to the cleared "UNITED" UTF Stem-Reduced (K123550). The indications, materials, design, manufacturing process and sterilization method of the subject device are identical to the cleared "UNITED" UTF Stem-Reduced (K123550).

Performance Data:

The mechanical properties of this device have been evaluated, and the analysis results shown that this subjected device (#12~#14) is not the worst case within all sizes of UTF Stem-reduced (#1~#14). This device modification would not affect the safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 30, 2013

United Orthopedic Corporation
% Ms. Fang-Yuan Ho
No 57, Park Ave 2, Science Park
Hsinchu 300
Taiwan

Re: K132207
Trade/Device Name: UTF Stem-reduced, Additional Sizes
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, KWY, LZO
Dated: July 31, 2013
Received: August 1, 2013

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510 (k) Number (if known): K132207

Device Name: UTF Stem-reduced, Additional Sizes

Indications for Use:

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This device is designed for cementless use.

Prescription Use ___x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices